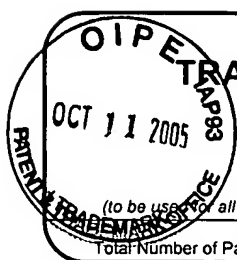


3738  
720

PTO/SB/21 (09-04)



# TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission

21

|                        |                  |
|------------------------|------------------|
| Application Number     | 10/002,595       |
| Filing Date            | November 1, 2001 |
| First Named Inventor   | SIRHAN, MOTASIM  |
| Art Unit               | 3738             |
| Examiner Name          | Phan, Hieu       |
| Attorney Docket Number | 020460-001600US  |

## ENCLOSURES (Check all that apply)

- |  |  |  |
|--|--|--|
| <input checked="" type="checkbox"/> Fee Transmittal Form<br><input type="checkbox"/> Fee Attached<br><input type="checkbox"/> Amendment/Reply<br><input type="checkbox"/> After Final<br><input type="checkbox"/> Affidavits/declaration(s)<br><input type="checkbox"/> Extension of Time Request<br><input type="checkbox"/> Express Abandonment Request<br><input checked="" type="checkbox"/> Information Disclosure Statement<br><br><input type="checkbox"/> Certified Copy of Priority Document(s)<br><input type="checkbox"/> Reply to Missing Parts/ Incomplete Application<br><input type="checkbox"/> Reply to Missing Parts under 37 CFR 1.52 or 1.53 | <input type="checkbox"/> Drawing(s)<br><input type="checkbox"/> Licensing-related Papers<br><input type="checkbox"/> Petition<br><input type="checkbox"/> Petition to Convert to a Provisional Application<br><input type="checkbox"/> Power of Attorney, Revocation<br><input type="checkbox"/> Change of Correspondence Address<br><input type="checkbox"/> Terminal Disclaimer<br><input type="checkbox"/> Request for Refund<br><input type="checkbox"/> CD, Number of CD(s) _____<br><input type="checkbox"/> Landscape Table on CD | <input type="checkbox"/> After Allowance Communication to TC<br><input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences<br><input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)<br><input type="checkbox"/> Proprietary Information<br><input type="checkbox"/> Status Letter<br><input checked="" type="checkbox"/> Other Enclosure(s) (please identify below):<br>Return Postcard<br>Cited References |
|--|--|--|

Remarks The Commissioner is authorized to charge any additional fees to Deposit Account 20-1430.

## SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

|              |                                    |          |        |
|--------------|------------------------------------|----------|--------|
| Firm Name    | Townsend and Townsend and Crew LLP |          |        |
| Signature    |                                    |          |        |
| Printed name | Nena Bains                         |          |        |
| Date         | 10/6/05                            | Reg. No. | 47,400 |

## CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below.

|                       |              |      |         |
|-----------------------|--------------|------|---------|
| Signature             |              |      |         |
| Typed or printed name | Landon Clark | Date | 10-6-05 |



PTO/SB/17 (12-04)

Effective on 12/08/2004.  
Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).

# FEE TRANSMITTAL

## For FY 2005

☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT (\$180)

**Complete if Known**

|                      |                  |
|----------------------|------------------|
| Application Number   | 10/002,595       |
| Filing Date          | November 1, 2001 |
| First Named Inventor | SIRHAN, MOTASIM  |
| Examiner Name        | Phan, Hieu       |
| Art Unit             | 3738             |
| Attorney Docket No.  | 020460-001600US  |

**METHOD OF PAYMENT (check all that apply)**☐ Check ☐ Credit Card ☐ Money Order ☐ None ☐ Other (please identify): \_\_\_\_\_☒ Deposit Account Deposit Account Number: 20-1430 Deposit Account Name: Townsend and Townsend and Crew LLP

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

☒ Charge fee(s) indicated below ☐ Charge fee(s) indicated below, except for the filing fee☒ Charge any additional fee(s) or underpayments of fee(s) under 37 CFR 1.16 and 1.17 ☒ Credit any overpayments

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**FEE CALCULATION****1. BASIC FILING, SEARCH, AND EXAMINATION FEES**

| Application Type | FILING FEES  |          | SEARCH FEES  |          | EXAMINATION FEES |          | Fees Paid (\$) |
|------------------|--------------|----------|--------------|----------|------------------|----------|----------------|
|                  | Small Entity | Fee (\$) | Small Entity | Fee (\$) | Small Entity     | Fee (\$) |                |
| Utility          | 300          | 150      | 500          | 250      | 200              | 100      |                |
| Design           | 200          | 100      | 100          | 50       | 130              | 65       |                |
| Plant            | 200          | 100      | 300          | 150      | 160              | 80       |                |
| Reissue          | 300          | 150      | 500          | 250      | 600              | 300      |                |
| Provisional      | 200          | 100      | 0            | 0        | 0                | 0        |                |

**2. EXCESS CLAIM FEES**

| Fee Description   | Small Entity |          |
|---|--------------|----------|
|   | Fee (\$)     | Fee (\$) |
| Each claim over 20 or, for Reissues, each claim over 20 and more than in the original patent            | 50           | 25       |
| Each independent claim over 3 or, for Reissues, each independent claim more than in the original patent | 200          | 100      |
| Multiple dependent claims   | 360          | 180      |

|                          |                     |                 |                      |                                  |                 |                      |
|--------------------------|---------------------|-----------------|----------------------|----------------------------------|-----------------|----------------------|
| <u>Total Claims</u>      | <u>Extra Claims</u> | <u>Fee (\$)</u> | <u>Fee Paid (\$)</u> | <u>Multiple Dependent Claims</u> | <u>Fee (\$)</u> | <u>Fee Paid (\$)</u> |
| _____ - 20 or HP = _____ | x _____             | = _____         |                      | _____                            |                 |                      |

HP = highest number of total claims paid for, if greater than 20

|                         |                     |                 |                      |
|-------------------------|---------------------|-----------------|----------------------|
| <u>Indep. Claims</u>    | <u>Extra Claims</u> | <u>Fee (\$)</u> | <u>Fee Paid (\$)</u> |
| _____ - 3 or HP = _____ | x _____             | = _____         |                      |

HP = highest number of independent claims paid for, if greater than 3

**3. APPLICATION SIZE FEE**

If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

|                     |                     |   |                 |                      |
|---------------------|---------------------|---|-----------------|----------------------|
| <u>Total Sheets</u> | <u>Extra Sheets</u> | <u>Number of each additional 50 or fraction thereof</u> | <u>Fee (\$)</u> | <u>Fee Paid (\$)</u> |
| _____ - 100 = _____ | / 50 = _____        | (round up to a whole number) x _____                    | = _____         |                      |

**4. OTHER FEE(S)**

Non-English Specification, \$130 fee (no small entity discount)

Other: Submission of Information Disclosure Statement

180

**SUBMITTED BY**

Signature

Registration No. 47,400  
(Attorney/Agent)

Telephone 415-576-0200

Name (Print/Type) Nena Bains

Date 10/6/05

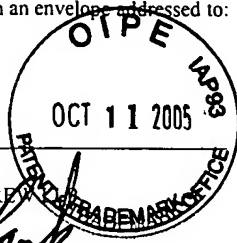
I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to:

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

On

10/6/05

TOWNSEND and TOWNSEND and CREW, LLP  
By: London Clark



PATENT  
Attorney Docket No.: 020460-001600US  
Client Reference No.: 240.90

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of:

SIRHAN, Motasim et al.

Application No.: 10/002,595

Filed: November 1, 2001

For: DELIVERY OF THERAPEUTIC  
CAPABLE AGENTS

Examiner: Phan, Hieu

Art Unit: 3738

SUPPLEMENTAL INFORMATION  
DISCLOSURE STATEMENT UNDER 37  
CFR §1.97 and §1.98

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

The references cited on attached form PTO/SB/08A&B are being called to the attention of the Examiner. Copies of the references [in compliance with the requirements of 1287 OG 163] are enclosed.

It is respectfully requested that the cited references be expressly considered during the prosecution of this application, and the references be made of record therein and appear among the "references cited" on any patent to issue therefrom.

As provided for by 37 CFR 1.97(g) and (h), no inference should be made that the information and references cited are prior art merely because they are in this statement and no

representation is being made that a search has been conducted or that this statement encompasses all the possible relevant information.

This IDS is being filed before the mailing date of the final Office Action or Notice of Allowance.

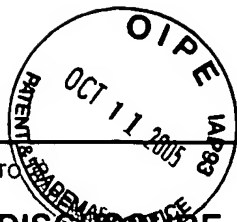
Please charge the IDS fee of \$180 to Deposit Account No. 20-1430. Please deduct any additional fees from, or credit any overpayment to, the above-noted Deposit Account.

Respectfully submitted,



Nena Bains  
Reg. No. 47,400

TOWNSEND and TOWNSEND and CREW LLP  
Two Embarcadero Center, Eighth Floor  
San Francisco, California 94111-3834  
Tel: 415-576-0200  
Fax: 415-576-0300  
NB/lle



Substitute for form 1449A&amp;B/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet **1** of **1****Complete if Known**

|                        |                  |
|------------------------|------------------|
| Application Number     | 10/002,595       |
| Filing Date            | November 1, 2001 |
| First Named Inventor   | SIRHAN, MOTASIM  |
| Art Unit               | 3738             |
| Examiner Name          | Phan, Hieu       |
| Attorney Docket Number | 020460-001600US  |

**U.S. PATENT DOCUMENTS+**

| Examiner<br>Initials* | Cite<br>No. <sup>1</sup> | Document Number                          | Publication Date<br>MM-DD-YYYY | Name of Patentee or<br>Applicant of Cited Document | Pages, Columns, Lines, Where<br>Relevant Passages or Relevant<br>Figures Appear |
|-----------------------|--------------------------|--|--------------------------------|--|---|
|                       |                          | Number Kind Code <sup>2</sup> (if known) |                                |  |   |
|                       |                          | US-                                      |                                |  |   |
|                       |                          | US-                                      |                                |  |   |
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|                       |                          | US-                                      |                                |  |   |
|                       |                          | US-                                      |                                |  |   |
|                       |                          | US-                                      |                                |  |   |

**FOREIGN PATENT DOCUMENTS**

| Examiner<br>Initials* | Cite<br>No. <sup>1</sup> | Foreign Patent Document   |                     |                                   | Publication Date<br>MM-DD-YYYY | Name of Patentee or<br>Applicant of Cited<br>Document | Pages, Columns, Lines,<br>Where Relevant<br>Passages or Relevant<br>Figures Appear | T <sup>6</sup>           |
|-----------------------|--------------------------|---------------------------|---------------------|-----------------------------------|--------------------------------|---|--|--------------------------|
|                       |                          | Country Code <sup>3</sup> | Number <sup>4</sup> | Kind Code <sup>5</sup> (if known) |                                |   |  |                          |
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|                       |                          |                           |                     |                                   |                                |   |  | <input type="checkbox"/> |

**NON PATENT LITERATURE DOCUMENTS**

| Examiner<br>Initials * | Cite<br>No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item<br>(book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s),<br>publisher, city and/or country where published. | T <sup>2</sup> |
|------------------------|--------------------------|---|----------------|
|                        | 0001                     | NGHIEM, et al.; "Tacrolimus and Pimecrolimus: From Clever Prokaryotes to Inhibiting Calcineurin and Treating Atopic Dermatitis;" <u>J Am Acad Dermatol</u> ; February 2002; pp. 228-241; Volume 46; Number 2; American Academy of Dermatology, Inc.                   |                |
|                        | 0002                     | Web page; "Ascomycin Macrolactams;" Ascomycin Macrolactams Fact Sheet; at URL= <a href="http://ascomycin.noneto.com/">http://ascomycin.noneto.com/</a> ;<br>printed March 11, 2004; 2 pages.  |                |
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|                       |  |                    |  |
|-----------------------|--|--------------------|--|
| Examiner<br>Signature |  | Date<br>Considered |  |
|-----------------------|--|--------------------|--|

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.